

Attorney Docket No.: **RTS-0350**
Inventors: **Freier and Roach**
Serial No.: **10/017,621**
Filing Date: **December 7, 2001**
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REMARKS

Claims 1, 2, and 4-20 are pending in the instant application. Claims 15-20 have been withdrawn from further consideration at this time. Claims 1, 2 and 4-14 have been rejected. Claims 1 and 2 have been amended. No new matter has been added by these amendments to the claims. Reconsideration is requested in light of these amendments to the claims and the following remarks.

I. Restriction Requirement

The Restriction Requirement wherein claims 1, 2 and 4-14 were placed into Group I, claims 15-18 were placed into Group II, and claim 19 and 20 were placed into Group III has been amended and then deemed proper and made Final. The Examiner has determined that the claims originally placed in Groups II and III are dependent upon claim 1 and are thus related. Accordingly, the Examiner has treated claim 1 as a linking claim which links Groups I through III and upon allowance of the linking claims, the restriction requirement shall be withdrawn and any linking claims depending from that claim shall be examined.

II. Rejection of Claims Under 35 U.S.C. 102/103

Claims 1, 2, 12 and 14 have been rejected under 35 U.S.C. 102(b) as anticipated by, or under 35 U.S.C. 103(a) as being obvious over, Okuda et al. (1992). The Examiner suggests that this paper discloses primers used to isolate PCTAIRE1 which possess 100% identity with SEQ ID NO: 3 of the instant

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application and thus would inherently possess the function of the claimed compounds. Applicants respectfully traverse this rejection.

At the outset, Applicants have amended claims 1 and 2, and, by dependency, claims 12 and 14, to recite that the compounds are modified. Support for this amendment can be found throughout the specification as filed but in particular at pages 14-21.

Okuda et al. (1992) disclose only primers targeted to PCTAIRE1 of SEQ ID NO: 3. Nowhere does this paper teach or suggest antisense compounds and their use to inhibit expression of PCTAIRE1, and most importantly, this paper fails to teach modified compounds and the use of such modified compounds. In order to anticipate or make obvious an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131 and 2143). This reference fails to teach the limitations of the claims as amended and cannot anticipate or make obvious the instant invention as now claimed. Withdrawal of this rejection is respectfully requested.

III. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 1, 2 and 4-14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Okuda et al. (1992), in view of Charasse et al. (1999), Taylor et al. (1999) and Baracchini et al. (U.S. Patent 5,801,154). The Examiner suggests it would have been *prima facie* obvious for one of ordinary skill to use the cDNA sequence of Okuda to generate antisense sequences as taught by Taylor et al. and Baracchini et al. for inhibition of PCTAIRE1

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expression and it further would have been obvious to employ the modifications as taught by Baracchini et al. The Examiner suggests that motivation is provided by Charasse et al. in teaching the role of this protein in regulating cell proliferation and differentiation and that a PCTAIRE1 null-protein eliminates PCTAIRE1 activity, indicating a desirability for antisense. The Examiner suggests that a reasonable expectation of success is provided by Okuda et al. and Taylor et al. Applicants respectfully disagree with the Examiner's conclusions regarding these references.

As discussed *supra*, the claims have been amended to recite that the compounds of the instant invention are modified compounds capable of inhibiting expression of PCTAIRE1. The primary reference cited, Okuda et al. (1992), discloses only the discovery of the PCTAIRE1 gene and its sequence. Nowhere does this paper teach or suggest the making of antisense compounds targeted to PCTAIRE1, of any type, and their use to inhibit gene expression. The secondary references cited fail to overcome the deficiencies in teaching of this primary reference.

Charasse et al. (1999) disclose the potential role of this gene in cell cycle-dependent activity. Although experiments were performed that examined the role of this gene in cell activity, including experiments where activity was inhibited, nowhere does this paper teach or suggest that antisense compounds or methods would be useful for modulating or inhibited PCTAIRE1 activity.

Taylor et al. (1999) is a review paper on the technology of antisense. Although the paper suggests that screening only 3-6 oligomers per target is sufficient to find one that inhibits the

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gene with 66-95% efficiency, this paper does not provide any assurance that a specific gene, such as PCTAIRE1 could be targeted successfully with antisense compounds as claimed.

Baracchini et al. disclose antisense compounds to an entirely different gene. Although this patent provides teaching of the general technology of antisense, nowhere does this paper provide one of skill with teaching of antisense to PCTAIRE1 of SEQ ID NO: 3.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly, the combination of prior art cited fails to establish a *prima facie* case of obviousness. There is no motivation provided in the references, as required, to combine references as claimed by the Examiner. Although two of the cited references teach the general art of antisense, the references cited that are specific to the gene claimed, have no mention or even suggestion that use of inhibition of the expression of this gene through antisense technology would be useful or even contemplated. Further, there is no teaching of antisense of any type to PCTAIRE1, leaving one of skill with no expectation of success for targeting this gene with antisense. It is only with the specification in hand that one of skill would

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understand how to target PCTAIRE1 with antisense and how such compounds could be used successfully to inhibit expression of SEQ ID NO: 3. Thus, this combination of prior art fails to establish a *prima facie* case of obviousness and withdrawal of this rejection is respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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